COVID-19 Evidence Accelerator Collaborative

Thursday, *June 11, 2020*

3rd Diagnostic Accelerator Call Summary

Diagnostic Evidence Accelerator:

The goal of the Evidence Accelerator collaboration is to bring together a community of data holders and analytic teams to work together to solve common problems, develop methods, and share lessons learned related to COVID-19.

There were 2 presentations and a discussion panel conducted at the 3rd Diagnostic Accelerator meeting.

1. Real-World Evidence Generation: Advancing Regulatory Science and Patient Access for IVDs (Danelle Miller, Roche/MDIC)
2. CDC Lab Reporting Requirement (Jason Hall, CDC)
3. Discussion on how to get useful data on test performance (Andrew Kress, Health Verity; Sadiqa Mahmood, Health Catalyst; Jeff Brown, Harvard Pilgrim; Ken Ehlert, United Health Group; Garrett Jenkinson, Mayo)

Real-World Evidence Generation: Advancing Regulatory Science and Patient Access for IVDs (Danelle Miller, Roche/MDIC)

The Medical Device Innovation Consortium (MDIC) released a framework titled Real-World Evidence Generation: Advancing Regulatory Science and Patient Access for In-Vitro Devices (IVDs). The framework intends to facilitate the use of real-world evidence (RWE) to accelerate the use of innovation of IVDs while providing patients and healthcare providers access to healthcare technology that are safe and effective. The framework includes 5 key elements

1. The current RWD and RWE landscape
2. The potential application of RWE for IVD premarket regulatory decision making
3. Potential application of RWD for IVD post market issues
4. A proposed approach to evaluate relevance and reliability of RWD to assess data quality for IVD regulatory decision
5. Study design and methods to generate valid scientific RWE for IVD regulatory assessment

The evidentiary requirement of the framework continues to be risk- based regardless of where the evidence originated. It uses RWE to be a source to reasonable assurance of IVD safety and effectiveness. Finally, the framework highlights the value of RWD across the total product life cycle. The IVD total product life cycle approach has 5 parts: design, analytical evaluation, clinical

evaluation, quality system, and post market surveillance. The framework is designed to be useful for clinical validity, analytical validity, early research and development work, feasibility studies, clinical trials, and performance claims. The framework includes different study design considerations such as observational clinical performance study, non-observational clinical performance study, virtual clinical performance study, schemes for RWD aid in diagnosis and follow up, RWD for an AI system as a binary test, and virtual clinical study for an AI system as a test with three category. The framework includes different use cases on how the FDA has used RWE in the IVD context.

The framework is available for public comment until June 15, 2020.

CDC Lab Reporting Requirement (Jason Hall, CDC)

HHS announced additional guidance in data reporting to be compliant under the CARES Act Section 18115. The act requires any laboratory that performs and analyzes COVID-19 diagnostic tests to report results. All labs have to report data for all tests completed within 24 hours to the state or local health department. There are three options for data submission: 1. Submitting directly to the state or local health department. 2. Submitting via a centralized platform. 3. Submitting data via a health information exchange (HIE). After submission of the data, the state will report it to the CDC which will complete the reporting requirement under the CARES Act. There are certain data elements that are laid out that the tester will have to follow, and the CARES Act makes it easier for testers to capture as many data elements as possible. CDC will make FAQ's available as soon as they are able to collect question and answer them.

Discussion on how we can get the data we need to understand COVID-19 test performance

Participants discussed 'solving the data dilemma'
- Potential to divide the problem into two parts: "scale and coverage" and "technical"
- The scale and coverage problem can be solved by increasing test volume and gathering data on the testing manufacturers that are used.
- The technical problem is that labs are not able to capture the manufacturers and tie that to the results of the tests.
- Needs bridge to link different data sources with each other for better data collection.

- What kind of integration exists for EHR and how does that integrate into various platforms
- Goal: develop an ecosystem where health systems, real world data sources, diagnostic companies, commercial laboratories, and regulator sources are combined.
  - Include data rights, patient matching, technology infrastructure, and centralized terminology implementation.

- Necessary data points: test orders, results, dates, standard codes, medical encounters (inpatient, outpatient, ED visit), demographics, diagnosis, treatment, and procedures

- Challenge: community testing data likely not available
- Different systems are able to answer different questions. Linking data and systems is important but researchers have to be careful not to introduce biases into the system when comparing positivity rates across systems.
- Potential important questions: how many test orders there are without results, how many results there are without orders, how many patients have a viral test and an antibody test
- Continuous patient data will provide helpful information

- Sensitivity and specificity important when comparing test manufacturer and test type
- Knowing what questions we are trying to answer is important to understand how sensitivity and specificity of the test will be viewed

- Challenge: how to deal with confounding and covariate variables

Next Steps for the Group

- Develop the 1st parallel analysis question to be considered at the next meeting
- Review the test performance question and answers
- Take the criteria discussed in this meeting and develop an outline for the next meeting

Next meeting: June 18, 2020 12- 1 PM ET